



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 21 2004

Cheng-I Lin, Ph.D.
President
Lin-Zhi International, Inc.
687 North Pastoria Avenue
Sunnyvale, CA 94085

Re: k031797
Trade/Device Name: Methadone Metabolite Enzyme Immunoassay
Regulation Number: 21 CFR 862.3620
Regulation Name: Methadone test system
Regulatory Class: Class II
Product Code: DJR; DLJ
Dated: August 25, 2003
Received: August 25, 2003

Dear Dr. Lin:

This SE Letter corrects the letter stamp dated October 10, 2003. The letter had only one Product Code. This letter corrects that with the addition of second Product Code DLJ.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

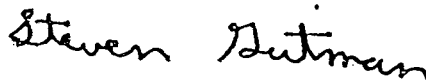
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, Address, and Contact

Lin-Zhi International, Inc.
687 North Pastoria Avenue
Sunnyvale, CA 94085
Phone: (408) 732-3856
Fax: (408) 732-3849

Contact: Cheng-I Lin, Ph.D.
President, R&D Director

Device Name and Classification

Classification Name: Methadone Metabolite test system, Class II, DJR
(91 Toxicology),
21CFR 862.3620
Common Name: Homogeneous enzyme immunoassay for the determination of
Methadone Metabolite (EDDP) levels in urine.
Proprietary Name: None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.' Methadone Metabolite Enzyme Immunoassay is substantially equivalent to the Methadone Metabolite Enzyme Immunoassay (By DRI/Microgenics Corp.), cleared under premarket notification K931780.

LZI's Methadone Metabolite Enzyme Immunoassay is identical or similar to its predicate in terms of intended use, method principle, device components, and clinical performance.

Device Description

LZI's Methadone Metabolite Enzyme Immunoassay is a ready-to-use, liquid reagent, homogeneous enzyme immunoassay. The assay uses specific antibody that can detect Methadone Metabolite (EDDP) in human urine with minimal cross-reactivity to various, common prescription drugs and abused drugs.

The assay is based on competition between Methadone Metabolite labeled with glucose-6-phosphate dehydrogenase (G6PDH) enzyme and free drug from the urine sample for a fixed amount of specific antibody. In the absence of free drug from the urine sample the specific antibody binds to the drug labeled with G6PDH enzyme causing a decrease in enzyme activity. The G6PDH enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

Intended Use

The Methadone Metabolite Enzyme Immunoassay is a homogeneous enzyme immunoassay with a 300 ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analyses of Methadone Metabolite in human urine.

Comparison to Predicate Device

LZI's Methadone Metabolite Enzyme Immunoassay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently, commercially marketed Methadone Metabolite Enzyme Immunoassay (K931780) by DRI/Microgenics Corporation.

The following table compares LZI's Methadone Metabolite Enzyme Immunoassay with the predicate device, Methadone Metabolite Enzyme Immunoassay by DRI/Microgenics Corp.

Similarities:

- Both assays are for qualitative and semi-quantitative determination of Methadone Metabolite in human urine.
- Both assays use the same method principle, and device components.

Differences:

- DRI/Microgenics assay uses 4 points calibration (0, 300, 1000, 2000 ng/ml) for semi-quantitative determination. LZI assay uses 5 calibrator set (0, 150, 300, 600, and 1000 ng/ml) for semi-quantitative determination.
- LZI assay uses 300 ng/ml calibrator as cut-off concentration. DRI/Microgenics assay uses 1000 ng/ml calibrator as cut-off concentration.

(Comparison to Predicate Device, continued)

Performance Characteristics

Feature	DRI's Methadone Metabolite EIA	LZI's Methadone Metabolite EIA
Within Run Precision:		
Qualitative:	<u>Mean Rate</u> <u>SD</u> <u>% CV</u>	<u>Mean Rate</u> <u>SD</u> <u>% CV</u>
Negative	620 4.1 0.7	Negative 297.9 2.16 0.73
300 ng/mL	776 4.4 0.6	225 ng/mL 354.0 2.43 0.69
1000 ng/mL	974 7.7 0.8	300 ng/mL 379.4 2.69 0.72
2000 ng/mL	1083 5.4 0.5	375 ng/mL 390.9 3.03 0.78
		1000 ng/mL 449.4 3.37 0.75
Semi-quantitative:	No data available	<u>Mean Conc.</u> <u>SD</u> <u>% CV</u>
		225 ng/mL 227.9 8.84 3.88
		300 ng/mL 304.9 13.73 4.50
		375 ng/mL 382.8 13.0 3.40
Run-To-Run Precision:		
Qualitative:	No data available	<u>Mean Rate</u> <u>SD</u> <u>% CV</u>
		Negative 296.7 2.2 0.74
		225 ng/mL 357.3 2.9 0.81
		300 ng/mL 377.2 1.8 0.47
		375 ng/mL 390.6 2.5 0.63
		1000 ng/mL 452.5 4.2 0.93
Semi-quantitative:	No data available	<u>Mean Conc.</u> <u>SD</u> <u>% CV</u>
		225 ng/mL 227.2 8.17 3.59
		300 ng/mL 298.4 10.8 3.62
		375 ng/mL 371.1 11.8 3.19
Sensitivity:	75 ng/mL	15 ng/mL
Accuracy:	Vs. a commercial EIA	Vs. GC/MS (n=139)
Positive Samples:	100 % agreement (GC/MS confirmed)	100 % agreement
Negative Samples:	100 % agreement	100 % agreement
Analytical Recovery:		
Qualitative:	No data available	100 % accuracy on positive vs. negative tests
Semi-quantitative:	No data available	Quantitates within $\pm 15\%$ of the nominal concentration between 30 ng/mL and 900 ng/mL.
		Average 95.0 % recovery at 225 ng/mL level (Cutoff -25%)
		Average 105.4 % recovery at 375 ng/mL level (Cutoff + 25%)
Specificity:	See attached DRI's Methadone Metabolite EIA package insert	Comparable to the predicate device.

Conclusion

LZI's Methadone Metabolite Enzyme Immunoassay was evaluated for several performance characteristics including precision, sensitivity, accuracy, analytical recovery, and specificity. All the studies showed acceptable results when compared to the predicate device.

We trust the information provided in this Premarket Notification [510(k)] submission will support a determination of substantial equivalence of the LZI's Methadone Metabolite Enzyme Immunoassay to other Methadone Metabolite test systems currently marketed in the United States.

Premarket Notification

Indications for Use Statement


510(k) Number (if known): K03 1797

Device Name: **Methadone Metabolite Enzyme Immunoassay**

Indications for Use:

The Methadone Metabolite Enzyme Immunoassay is a homogeneous enzyme immunoassay with a 300 ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analyses of Methadone Metabolite in human urine. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

The Methadone Metabolite Enzyme Immunoassay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.


Division Sign-Off *for Jean Cooper*

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K03 1797

Concurrence of CDRH, Office of Device Evaluation (ODE)



Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)